REMARKS

Claims 38-45 and 47-73 are pending. Claims 1-37 and 46 are cancelled. Claims 38, 47-49, 57, 58, 61-64, 69 and 70 are amended. No new matter has been added.

The Examiner rejected claims 38-53 and 69-73 under 35 USC §103(a) as being unpatentable over Moll (U.S. Patent No. 5,309,896) in view of either Edwards (U.S. Patent No. 5,293,869 or 5,309,910) or Imran (U.S. Patent No. 5,156,151). Applicants respectfully traverse this rejection. The combination of Moll with either Edwards or Imran does not teach or suggest the invention of claims 38-53 and 69-73, as amended.

Four independent claims are pending. Claim 38 claims a method of forming a lesion in heart tissue of a patient to treat atrial fibrillation, ***consisting essentially of*** the steps of original claim 38: providing an electrophysiological ablating device comprising at least one electrode; creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity; passing the electrode through the opening; positioning the electrode adjacent to heart tissue; and ablating the heart tissue with the electrode to create a lesion in the heart tissue while the heart is beating to treat atrial fibrillation. Claims 47, 69 and 70 claim methods of forming a lesion in tissue of a patient's heart that includes, among other steps, the step of providing a device comprising a rigid shaft having a distal end and a proximal end, a flexible tip attached to the distal end of the shaft, and at least one ablating element carried on the flexible tip.

Turning to the art cited in the rejection, Moll is concerned with inflatable retraction devices used in laparoscopic surgery. As is described in the text of Moll:

> The present invention relates to an ***inflatable retraction device that mechanically retracts organs to provide access to treat tissues***. More specifically, the invention is concerned with using a retraction device that retracts organs or tissues by means of an inflatable chamber. The retraction device is introduced laparoscopically in a collapsed state into the body and, once in place, inflated to engage an extensive area of the organ to be retracted, and to gently retract or displace the organ without damaging it.

> During laparoscopic treatment procedures, a retraction device according to the invention retains its expanded condition, and hence its ability to provide retraction, while providing access for surgical instruments through itself to the tissue being or allowing a or tissue to be brought inside itself for treatment.

Moll, column 2:64-3:10 (emphasis added). Moll suggests a number of procedures can be improved by using such a device to retract the bowel, the lungs, the liver, and the brain, for example. In addition, Moll suggests that the pericardium can be retracted using

> a small, oblate version of a Type I or Type II retraction device to displace the pericardium 403 from the heart 408 .... Displacement of the pericardium allows the outer surface 413 of the heart 408 to be observed, and such procedures as endocardial mapping, ***ablation***, transmyocardial revascularization, and defibrillation to be carried out. These procedures have until now been difficult to do laparoscopically because access to the surface of the heart 408 is obstructed by the pericardium 403.

Moll, col 21:49-60 (emphasis added). The Type I retraction device of Moll includes a two chamber retractor, where the first chamber is inflated to retract an organ and the second chamber is used to maintain the organ in its retracted state when the first chamber has been deflated or punctured to permit access to treat tissue with a device. See Moll Figures 1-5 and col 3:37-58. The Type II retraction device of Moll is an inflatable chamber that has an elastomeric window through which an instrument may be passed. The instrument is then used to treat tissue that has been pulled into the inflatable chamber through a separate window or the instrument is passed through the second window to treat tissue on the other side of the retractor. See Moll Figure 6 and col 4:3-16.

The obviousness rejection relies upon combining Moll with Edwards and Imran. Edwards and Imran each describe ablation catheters designed to be introduced into a peripheral artery, such as the femoral artery, and snaked internally through the aorta and at least the aortic valve to a position within the heart prior to ablating tissue.

The combination of Moll with either Edwards or Imran does not teach or suggest the invention of claims 38-53. As amended claim 38 requires that a method "consisting

essentially of" the enumerated steps. This type of transition phrase indicates that the method is limited to steps that do not materially affect the basic and novel characteristics of the claimed method. See PPG Industries v. Guardian Industries Corp., 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998); MPEP §2111.03. Because the step of retracting the pericardium taught in Moll materially affects the basic and novel characteristic of the claimed method, claim 38 is patentable over Moll and the combination of Moll with either Edwards or Imran.

More specifically, whether a Type I or Type II retractor described in Moll is used, the user's ability to manipulate an instrument either through the retractor (in the case of Type I) or around the retractor (in the case of Type II) will be limited. The specification of Moll describes the instrument probe 438 as being "passed through the pericardium 403 and the main chamber 411 of the retraction device 401, [and] piercing a first window 443 and a second window 448 of the retraction device." Moll 22:29-32. The ability to manipulate will be limited by passing the instrument through two windows prior to contacting the tissue to be ablated.

In contrast, as is discussed in the specification of the current application, the device design permits the user to manipulate the instrument precisely: "The relatively short distance between the user and the interior of chamber C, as well as the rigidity of shaft 312, facilitate exceptionally controllable and precise manipulation of the device relative to endovascular catheter-based electrophysiology devices." Stevens Publication No. 20030225402 ¶ 156. Precision is critical when using an instrument to create ablation lines to treat atrial fibrillation. It is not simply enough to spot ablate; the user needs to create lines at specific locations to create a conduction pathway: "precise incisions or ablation lines may be made in the myocardium to create a directed conduction pathway between the sinoatrial node and the atrioventricular node to perform a Cox 'maze' procedure." Stevens Publication No. 20030225402 ¶ 158. The use of a retractor like those described in Moll materially affects the basic and novel characteristic of the claimed method.

Further, Moll describes that the retractor may be used to displace the pericardium so as to perform "ablation", among other procedures. The type of ablation performed, however, is not discussed. Ablation can be performed to treat conditions, such as Wolff-Parkinson-White Syndrome, wherein the ablation performed are spot ablations, or ablations at one location, as opposed to the line ablations required to treat atrial fibrillation. Moll is silent as to the type of ablation that may be performed in conjunction with the use of its retractor.

Further, claim 38 requires the step of ablating the heart tissue while the heart is beating, and Moll does not teach or suggest performing ablation on a beating heart. As described above, Moll simply references that once the pericardium is retracted using a Type I or Type II retractor, "ablation" may be performed. And while both Edwards and Imran describe catheter-based ablation devices for ablating heart tissue while the heart is beating, there is no suggestion or motivation to combine these catheter-based devices with Moll.

The Examiner states that one of ordinary skill in the art would combine Moll with Edwards or Imran "in order to avoid more costly surgical intervention and trauma." Neither Moll, Edwards or Imran teach, however, suggest or motivate one skilled in the art to combine based on this reason. Moll discusses that a larger retractor should be used when retracting an organ to avoid causing trauma to the organ. See Moll col 1:36-41; col 12:43-46; col 17:33-38. Such a teaching, however, does not provide motivation or suggest to one skilled in the art to combine the beating heart teaching of Edwards and Imran with Moll so as to avoid trauma or costly surgical intervention.

Further, one skilled in the art is not provided that motivation or suggestion by Edwards or Imran (or for that matter Desai or Lundquist) as these devices already avoid costly surgical intervention and trauma by performing their ablation procedures via a catheter snaked through peripheral arteries to ablate heart tissue from the inside of the heart. Nothing in either reference suggests or motivates one skilled in the art to combine them with Moll.

As such, Applicants request that the Examiner withdraw the obviousness rejection as to claims 38-53.

Turning to claims 69-73, Applicants submit that these claims are both novel and non-obvious over Moll, Edwards or Imran, or the combination of any of these references. Claim 69 claims a method of forming a lesion in heart tissue of a patient, including the steps of providing a device comprising ***a rigid shaft having a distal end and a proximal end, a flexible tip attached to the distal end of the shaft, and at least one ablating element carried on the flexible tip***; creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity; passing the distal end of the device through the opening; positioning the distal end of the device adjacent to heart tissue; and delivering energy via the device to the distal end of the device to create a lesion in the heart tissue while the heart is beating.

Moll depicts at Figure 15 an instrument probe 438 that is described as being passed through the chest wall to contact the surface of the heart via the first window and second window of a retraction device. Moll, col 22:26-28. The instrument probe 438 is not shown or described as having a flexible tip or as having at least one ablating element carried on the flexible tip. Imran describes a flexible element 221 that carries electrodes 217, 218 and is attached to the end of a ***flexible*** tubular member 36. See Imran Figure 19 and col 11:61-col 12:9. Imran does not describe a rigid shaft having a flexible tip attached at its distal end that carries at least one electrode. Similarly, Edwards describes a probe 12 having a ***flexible*** catheter 18 and an flexible electrode array 20 that extends from the flexible catheter, see, e.g., Edwards Figures 1, 2 and col 3:42-62, but does not describe a rigid shaft having a flexible tip attached at its distal end that carries at least one electrode. Thus, neither Moll, Edwards or Imran describes or depicts the device claimed in claim 65, and as such neither reference describes the providing step or the passing step of claim 65.

As to combining Moll with either Edwards or Imran, nothing in any of the references motivates or suggests such a combination. Moll's focus is on its inventive retraction device; Moll does not describe the instrument probe in any detail. Edwards and Imran are catheter-based devices that need to be flexible over their length in order to be maneuvered into the

appropriate location within the blood vessels through which they travel. As such, Applicants submit that claims 65-69 are allowable and request the Examiner to indicate as such.

The Examiner rejected claims 54-56 under 35 USC §103(a) as being unpatentable over Moll in view of Edwards or Imran and further in view of Desai (U.S. Patent No. 4,940,064). Applicants respectfully traverse this rejection for at least the reason that claims 54-56 depend from claim 47, which, as described above, is patentable over the cited art. As a result, Applicants request the Examiner to withdraw the rejection.

The Examiner rejected claims 57-68 under 35 USC §103(a) as being unpatentable over Moll in view of Edwards or Imran and further in view of Lundquist (U.S. Patent No. 5,322,064). Applicants respectfully traverse this rejection for at least the reason that claims 57-68 depend from claim 47, which, as described above, is patentable over the cited art. In addition, as discussed in connection with the rejection of claims 69-73, nothing in Moll or Edwards or Imran suggests combining these references with Lundquist. Similar to Edwards and Imran, Lundquist discloses a catheter-based ablation catheter designed to be introduced into a peripheral artery, such as the femoral artery, and snaked internally through the aorta and at least the aortic valve to a position within the heart prior to ablating tissue. And like, Edwards and Imran, Lundquist depicts a flexible catheter 21 with a flexible tip 28. Lundquist does not describe the claimed rigid shaft having a flexible tip attached at its distal end that carries at least one electrode.

Further, Lundquist, like Edwards and Imran does not provide the motivation to combine suggested by the Examiner, as Lundquist already provides a device that avoids costly surgical intervention and trauma. Because nothing in either Moll or Lundquist suggests or motivates one skilled in the art to combine the references, Applicants request the Examiner to withdraw the rejection.

Finally, the Examiner rejected claims 38-53 and 69-73 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-11 of US Patent No. 6161543 (Cox). Applicants traverse the rejection for the same reasons discussed in

the earlier filed response dated May 16, 2003, to the Office Action mailed December 18, 2002, repeated below, though updated to reflect changes to the claims.

Obviousness-type double patenting requires rejection of an application claim when the ***claimed*** subject matter is not patentably distinct from the ***claims*** of the patent in question. See MPEP §804 II.B.1 (page 800-22 (8th ed. rev. 1)). In this case, the claimed subject matter of the application is patentably distinct from the claims of the Cox patent. The sole independent claim of Cox, claim 1, reads as follows:

> A method of ablating epicardial tissue around the pulmonary veins, comprising the steps of:
> providing at least one ablation device having at least one ablating element;
> introducing the ablation device into the patient's chest;
> positioning the ablating element in contact with a location ***on an epicardial surface of the heart***; and
> ablating tissue to form a lesion ***around the pulmonary veins*** with the at least one ablating element positioned at the location on the epicardial surface to form at least part of the lesion around the pulmonary veins.

Note that claim 1 of Cox requires forming a lesion ***around the pulmonary veins*** with the at least one ablating element ***positioned at the location on the epicardial surface*** to form at least part of the lesion around the pulmonary veins. As is shown below, pending independent claim 38 does not claim ablating an epicardial surface; nor does it claim ablating around the pulmonary veins. Claim 38 is presented below.

38. A method of forming a lesion in heart tissue of a patient to treat atrial fibrillation, consisting essentially of:
providing an electrophysiological ablating device comprising at least one electrode;
creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity;
passing the electrode through the opening;
positioning the electrode adjacent to heart tissue; and
ablating the heart tissue with the electrode to create a lesion in the heart tissue while the heart is beating to treat atrial fibrillation.

Further, claim 38 includes, among other differences, a step that Cox does not claim: "ablating the heart tissue with the electrode to create a lesion in the heart tissue ***while the heart is beating to treat atrial fibrillation***." Not one of the claims in Cox describe this step. Similarly, claims 47, 63 and 70 claim ablating heart tissue to create a lesion while the heart is beating, which Cox does not claim. As a result, Applicants submit that claims 38-53 and 69-73 of the pending application are patentably distinct from claims 1-11 of Cox as the claims of Cox would not have rendered claims 38-53 and 69-73 obvious to one of ordinary skill in the art.

The Examiner has, for each of the pending claims, pointed out in the specification of Cox where the elements of the pending claims find support. It is well-settled, however, that "[w]hen considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, ***the disclosure of the patent may not be used as prior art***." MPEP §804 II.B.1 (page 800-22 second column); General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1280-81 (Fed. Cir. 1992). As a result, reliance on the specification of the Cox patent is not appropriate. Applicants respectfully submit the obviousness-type double patenting rejection over the Cox patent is obviated, and request it be withdrawn.

Applicants request that the Examiner contact the undersigned if a discussion of the issues would advance the prosecution of the application.

Respectfully submitted,

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